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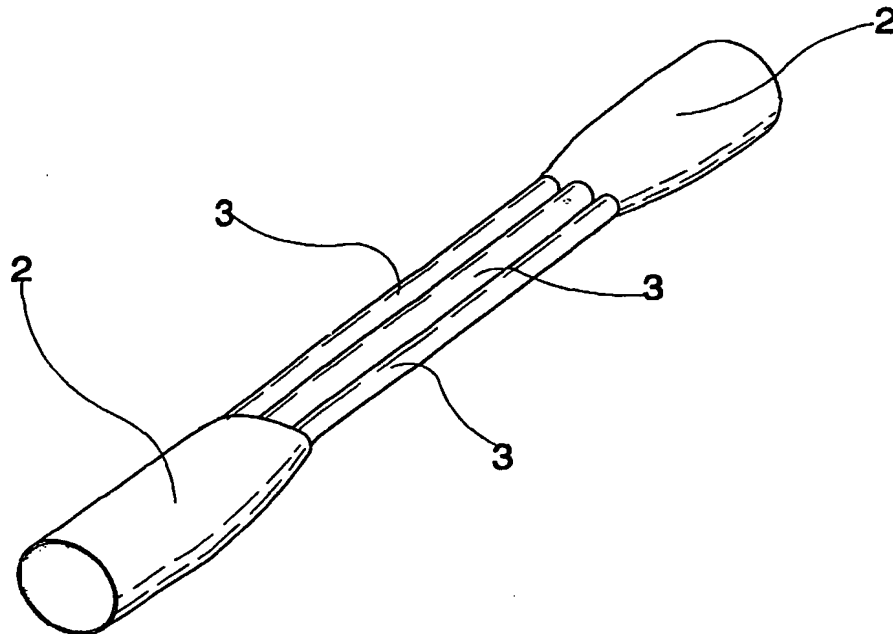
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(54) Title: A PROSTHESIS FOR LARGE BLOOD VESSELS



(57) Abstract: A prosthesis for large blood vessels comprises a main conduit (2), at least one tract of which is subdivided into a plurality of small conduits (3) located parallel one to another.

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Description
A Prosthesis for Large Blood Vessels.

Technical Field

The invention relates to the field of prostheses used in treatment of thoracic-abdominal aneurysm.

Background Art

The thoracic-abdominal aneurysm is largely a progressive yielding, fatal upon
5 breaking, of the walls of the thoracic and abdominal aorta. As there is no possible
medical therapy available, the pathology can only be treated by surgical
intervention, which involves a large-scale thoracic laparotomy and substitution
of the dilated tract with a straight tubular prosthesis. The visceral blood vessels
and sometimes the intercostal arteries are connected to the prosthesis.

10 The surgical operation is carried out usually according to two main techniques,
often used in combination.

The first of these techniques, also known as the De Bakey method, involves
clamping (hemostasis) of the tract of aorta downstream of the aneurysm, a first
sectioning of the aorta itself and the suturing of the prosthesis to the first section,
15 and the clamping of the tract of aorta upstream of the aneurysm, a second
sectioning of the aorta and the suturing (anastomosis) of the prosthesis to the
second section. Then the visceral branches are sutured to the prosthesis with or
without interpositioning of prosthetic segments. This technique exposes the
patient to quite long operations with relevant haemorrhaging, but guarantees good
20 blood circulation downstream of the aneurysm.

The second technique, also known as the Crawford method, is based on the speed

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of performance of the operation. The aorta is clamped upstream and downstream of the aneurysm. The aorta is sectioned upstream and downstream of the aneurysm, hemostasis is performed on any arteries connected to the sectioned tract of aorta, and the prosthesis is applied with rapid suturing to the two sections.

- 5 The visceral and intercostal arteries from the sectioned tract of aorta are then sutured to the prosthesis, preferably without interpositioning of prosthetic segments in order not excessively to extend operation time. The technique implies that during the operation the circulation downstream of the thorax is practically stopped. If possible, in anastomosis of the visceral and intercostal
- 10 arteries, patches of aortic sections surrounding the original connection points of the arteries are re-used.

Although the results obtained using the techniques are satisfactory in a majority of the cases, with the patients' progressing to full recovery, there are however not inconsiderable risks connected to the importance of the surgical operation itself.

- 15 The rate of mortality during or immediately following surgery, together with post-operational respiratory difficulties and kidney failure, can reach up to 20%. There is also a risk of about 20% of paraplegia, leading many patients to refuse to undertake the operation.

- 20 Paraplegia, as well as the other complications, is essentially due to a blockage in arterial circulation to the lower parts of the body. This blockage, which is of a length correlated to the difficulty of performance of the operation, can obviously lead to medullar ischemia and therefore to paralysis of the lower limbs.

- To limit the risk of paraplegia temporary aortic by-passes are used, with extracorporeal circulation tubing taking blood from upstream of the aneurysm
- 25 and sending it to the lumbar and hypogastric arteries. The inflow of blood to these arteries guarantees a sufficient vascularization of the medulla and the abdominal organs, very considerably reducing risks of ischemia. The use of

extracorporeal circulation, however, involves considerable use of anticoagulants, especially if a pump is used, as is sometimes the case; in all cases, however, long operation times are needed.

The main aim of the present invention is to provide a prosthesis for large blood vessels which limits operation times for treatment of thoracic-abdominal aneurysm, thus also reducing duration of hemostasis in the aorta.

A further aim of the present invention is to maintain the blood circulation downstream of the aneurysm during the anastomosis operation on the various blood vessels branching off from the affected tract.

Disclosure of Invention

Further characteristics and advantages of the present invention will better emerge from the detailed description that follows of a prosthesis for large blood vessels, in a preferred but non-exclusive embodiment of the invention, illustrated purely by way of a non-limiting example in the accompanying figures of the drawing, in which:

figure 1 is a perspective view of a prosthesis according to the present invention;
figure 2 is a first example of use of the prosthesis of figure 1;
figure 3 is a second example of use of the prosthesis of figure 1;
figure 4 is a third example of use of the prosthesis of figure 1;
figure 5 is a fourth example of use of the prosthesis of figure 1.

With reference to the figures of the drawings, 1 denotes in its entirety a prosthesis according to the present invention. It comprises a main conduit 2, at least a tract of which is subdivided into a plurality of small conduits 3 located parallel to one another.

The small conduits 3 each exhibit an internal calibre which is smaller than the main conduit 2 and the overall section of the small conduits 3 is about the same as that of the main conduit 2. The flow of blood entering the main conduit 2 is

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sub-divided into the small conduits 3.

The small conduits 3 are also independent of one another. They exhibit lateral walls which are distinct one from another, so that they can be manipulated and used separately. The small conduits 3 are for example three in number, one of which may exhibit a larger calibre than the remaining two thereof.

The main conduit 2 and the small conduits 3 are made of a bio-compatible material which has only a small elastic deformability in a transversal direction and a considerable elastic deformability in a longitudinal direction.

The application of the prosthesis of the present invention can be made in the following stages.

After having approximated the length of prosthesis required, distal clamping is performed and distal anastomosis 10a to the aorta 10 is carried out. Subsequently proximal clamping is performed and the aneurysm opened with clamping of the branching vessels in the tract affected by aneurysm. Proximal anastomosis 10b is then performed. Once the two suturing operations have been carried out, the clamps can be removed and abdominal and medullar blood circulation restored.

In this calm situation the anastomosis of the branch vessels 12 from the tract subject to aneurysm can be carried out; the branch vessels 12 are sutured to the prosthesis while blood circulation is maintained through the other small conduits

3. As can be seen in figure 2, the branch vessels 12 can be sutured with the use of small patches 11 of original aortic matter surrounding the ends of the vessels and cut away with the vessels themselves. These can be sutured onto the largest of the small calibre conduits 3. If this technique is not possible, the small calibre conduits 3 can be used for end-to-end anastomosis between the prosthesis and the branch vessels 12 originating from the tract affected by aneurysm, while circulation is maintained through the small conduit 3 of largest calibre (figures 3, 4, 5). Alternatively a small conduit 3 can be used to create a temporary by-pass

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of the prosthesis itself.

The application of the prosthesis of the present invention guarantees a high degree of liberty of action to perform the required anastomosis, whether pre-determined or decided during the course of the actual operation.

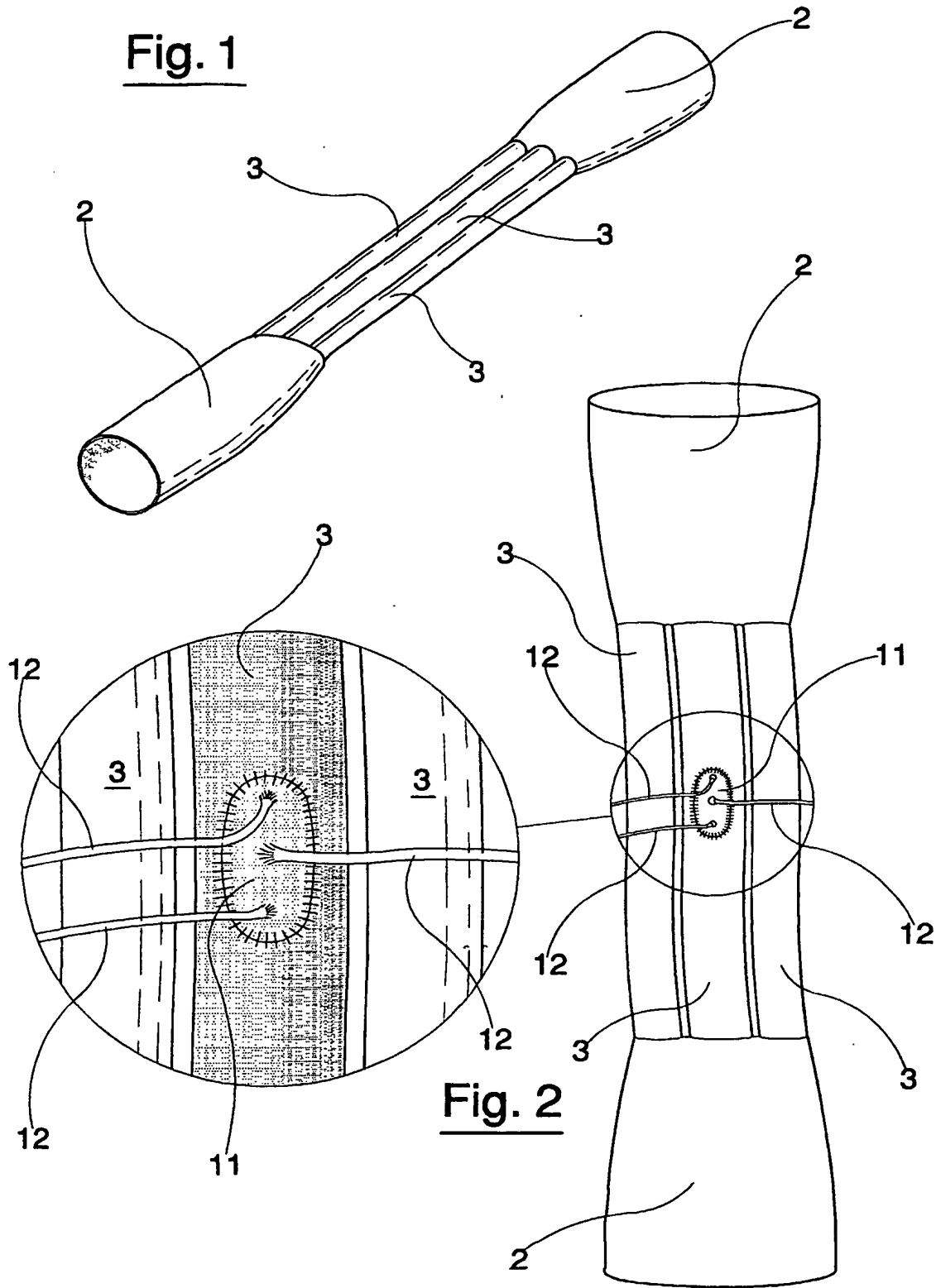
- 5 The duration of the hemostasis is thus limited to the time required for carrying out the proximal and distal anastomosis of the prosthesis to the aorta, reducing by a very considerable degree the risk of medullar or abdominal ischemia.

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Claims.

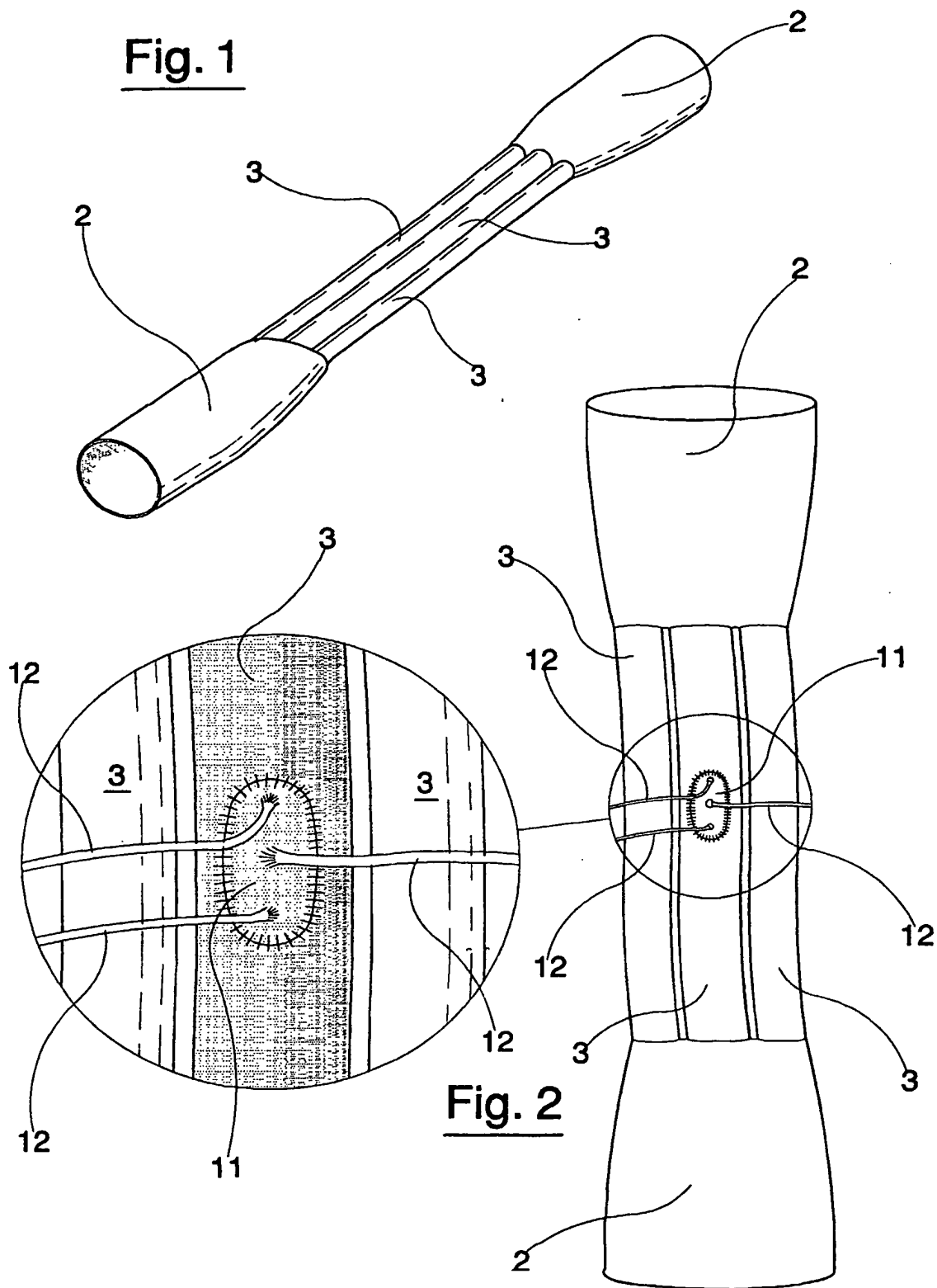
- 1). A prosthesis for large blood vessels, wherein the prosthesis comprises a main conduit (2), at least one tract of which is subdivided into a plurality of small conduits (3) located parallel one to another.
- 2). The prosthesis of claim 1, wherein the small conduits (3) each have an
5 internal calibre which is smaller than an internal calibre of the main conduit (2).
- 3). The prosthesis of claim 2, wherein an overall section which is a sum of sections of the small conduits (3) is approximately equal to a section of the main conduit (2).
- 4). The prosthesis of claim 3, wherein the small conduits (3) are independent one
10 from another.
- 5). The prosthesis of claim 2, wherein the small conduits (3) are three in number.
- 6). The prosthesis of claim 5, wherein a small conduit of the small conduits (3) exhibits a greater calibre than two of the small conduits (3).
- 7). The prosthesis of claim 6, wherein the main conduit (2) and the small conduits
15 (3) are made of a bio-compatible material which exhibits a small elastic deformability in a transversal direction thereof and a greater elastic deformability in a longitudinal direction thereof.

Fig. 1



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Fig. 1



INTERNATIONAL SEARCH REPORT

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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	AU 729 443 B (BOSTON SCIENT LTD) 1 February 2001 (2001-02-01) figures 16,18	1-5
X	US 6 398 807 B1 (HAVERKOST PATRICK A ET AL) 4 June 2002 (2002-06-04) column 3, line 8 - line 25	1,2,4
X	US 6 409 757 B1 (TANNER HOWARD M ET AL) 25 June 2002 (2002-06-25) column 7, line 14 - line 42	1,3,4
A	WO 02 35988 A (PRODESCO ; GREENHALGH E SKOTT (US)) 10 May 2002 (2002-05-10) claim 10; figure 9	1-7

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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Information on patent family members

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
AU 729443	B	01-02-2001	US 5800514 A	01-09-1998
			AU 729443 B2	01-02-2001
			AU 757985 B2	13-03-2003
			AU 3208797 A	09-12-1997
			CA 2256324 A1	27-11-1997
			CA 2422915 A1	27-11-1997
			EP 0910310 A1	28-04-1999
			JP 3442402 B2	02-09-2003
			JP 11511679 T	12-10-1999
			WO 9743983 A1	27-11-1997
			US 6136022 A	24-10-2000
			US 2003130728 A1	10-07-2003
			US 2003078650 A1	24-04-2003
			US 2003196717 A1	23-10-2003
			US 6596023 B1	22-07-2003
			US 5904714 A	18-05-1999
<hr/>				
US 6398807	B1	04-06-2002	AU 2978401 A	07-08-2001
			CA 2392245 A1	02-08-2001
			EP 1251799 A1	30-10-2002
			JP 2003521312 T	15-07-2003
			WO 0154621 A1	02-08-2001
			US 2002111674 A1	15-08-2002
			US 6622604 B1	23-09-2003
			US 6652571 B1	25-11-2003
<hr/>				
US 6409757	B1	25-06-2002	EP 1231870 A1	21-08-2002
			JP 2003509113 T	11-03-2003
			WO 0119286 A1	22-03-2001
<hr/>				
WO 0235988	A	10-05-2002	AU 3077002 A	15-05-2002
			EP 1343435 A2	17-09-2003
			WO 0235988 A2	10-05-2002
			US 2002052649 A1	02-05-2002
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Fig. 1

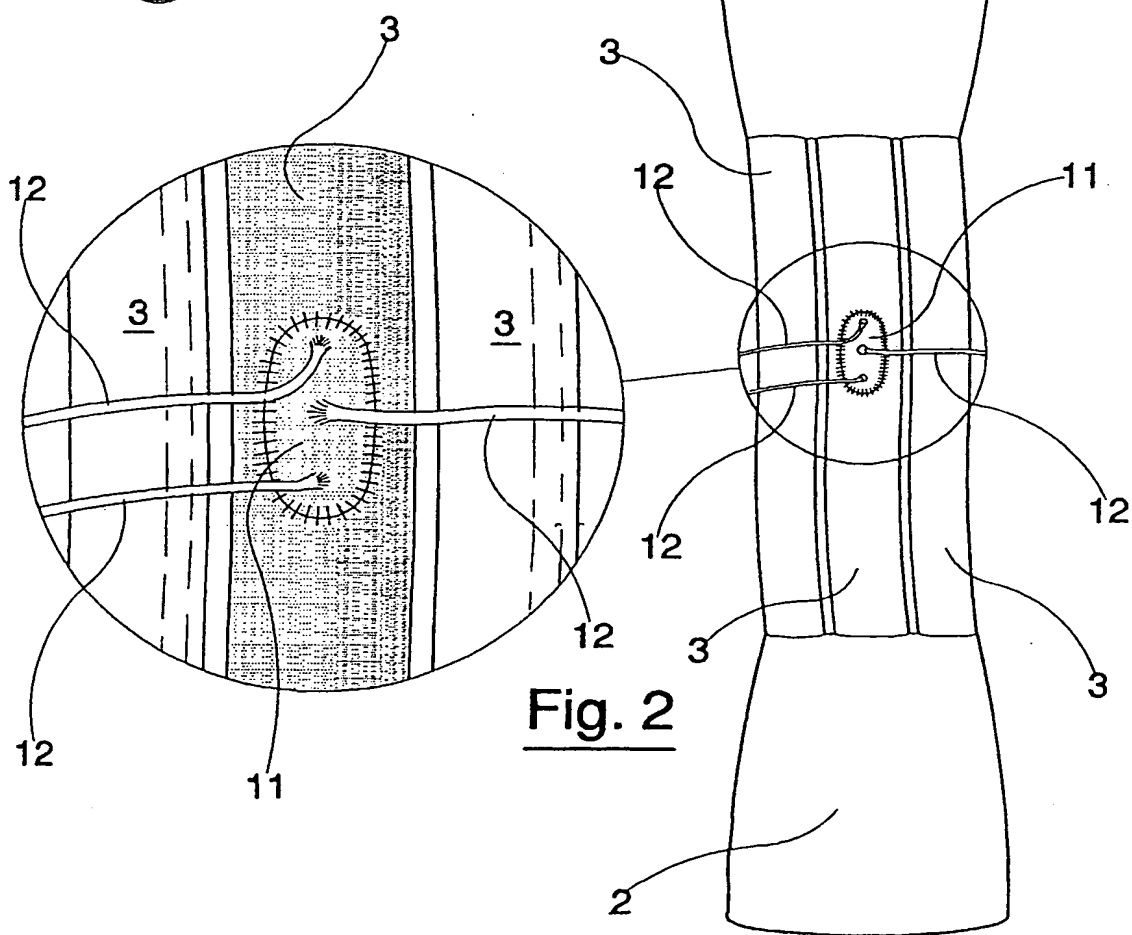
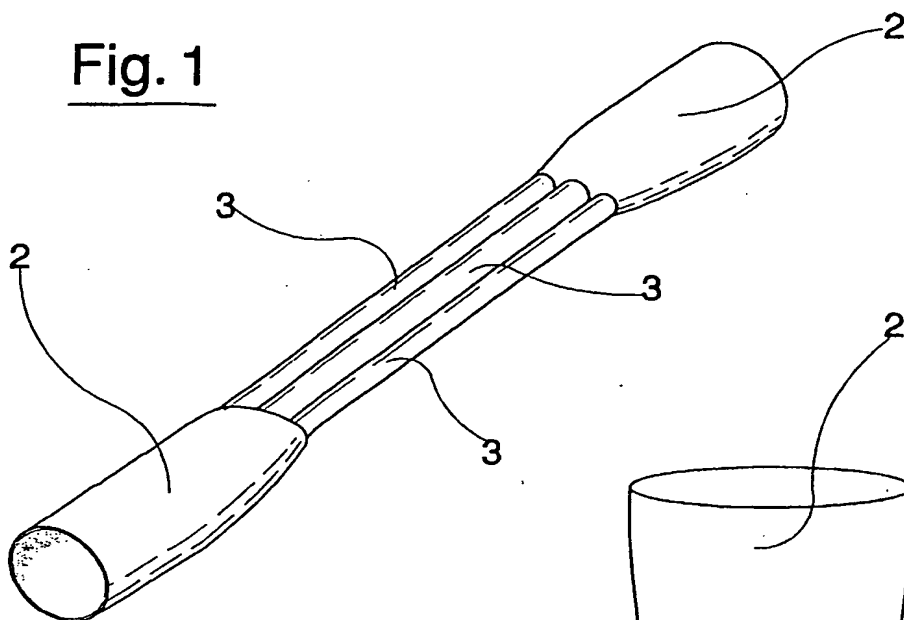


Fig. 2

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Fig. 1

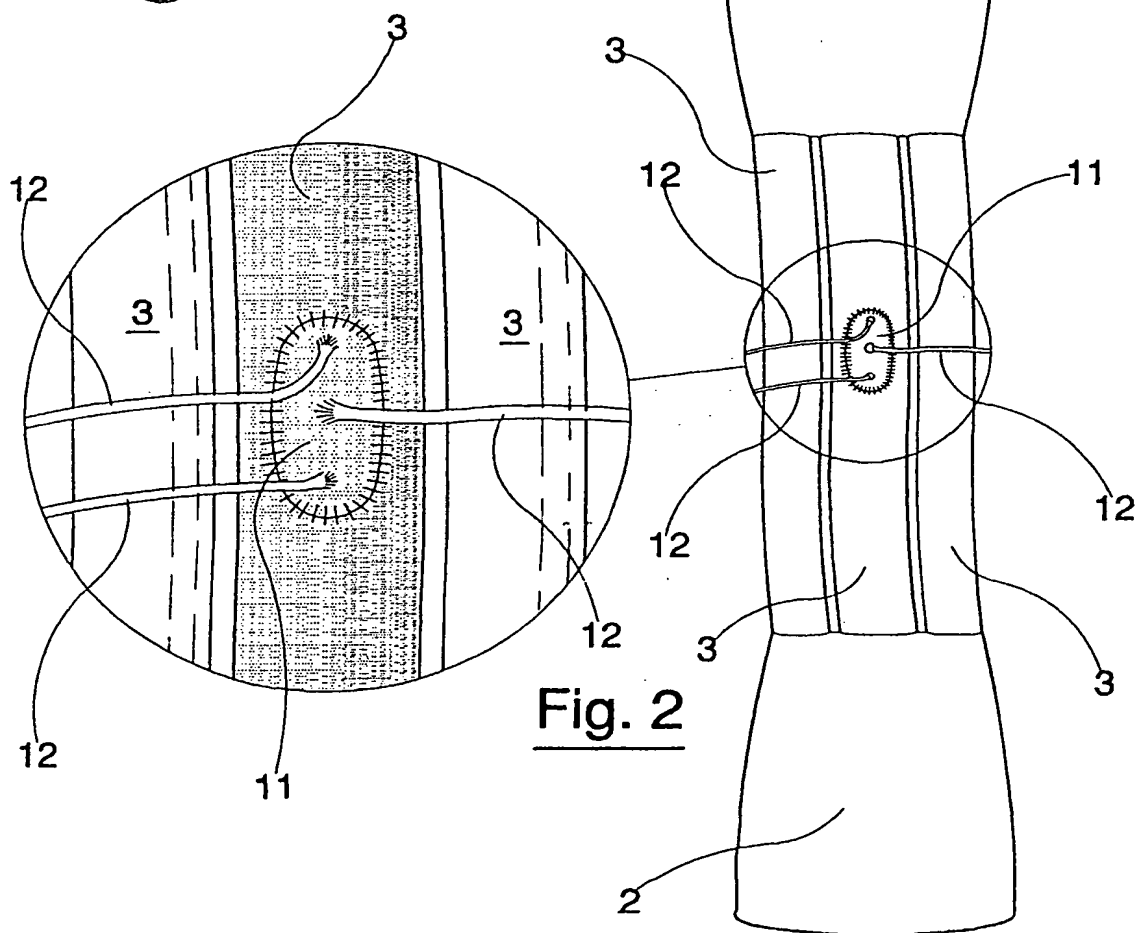
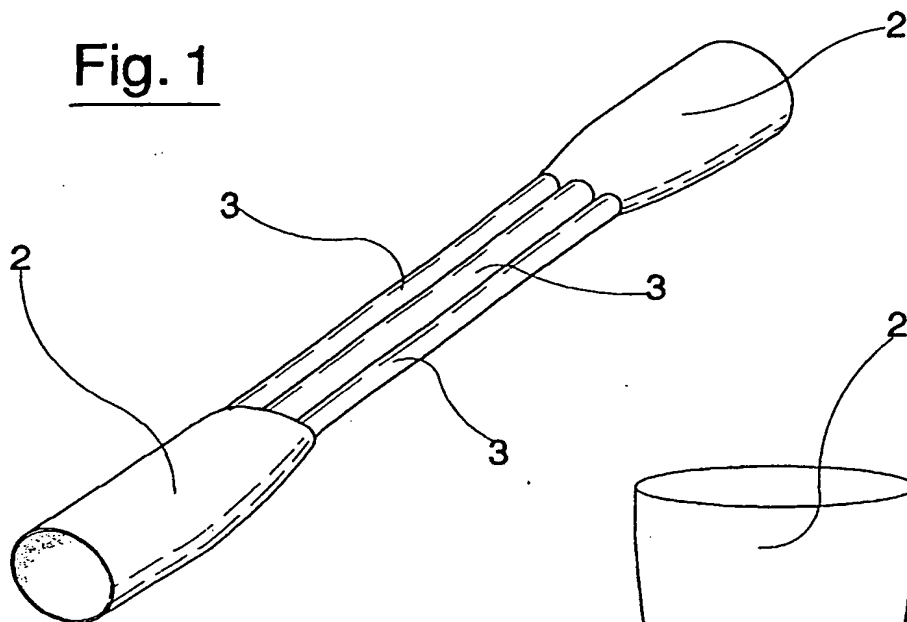


Fig. 2